UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

| | |
|---|---|
| PENNSYLVANIA EMPLOYEE BENEFIT TRUST FUND, on behalf of itself and all others similarly situated,<br><br>Plaintiffs,<br><br>v.<br><br>ZENECA, INC. and ASTRAZENECA PHARMACEUTICALS, L.P.,<br><br>Defendants. | No. 05-075-SLR |

**PLAINTIFFS' MOTION FOR JUDICIAL NOTICE OF FDA RULINGS**

Plaintiffs respectfully move that the Court take judicial notice of the documents appended hereto.

In the September 9, 2005 hearing on Defendants' motion to dismiss the complaint, Defendants argued that the Food and Drug Administration ("FDA") approved Nexium as superior to Prilosec. Specifically, Defendants argued:

> . . . By approving a 40-milligram dose of Nexium for healing erosive esophagitis, the FDA relied upon and necessarily found that the studies that plaintiffs want to say are skewed and slanted in their words are, in fact, adequate and well controlled studies to the point that the FDA approved summaries of these studies on the label that appears necessarily by law covers every prescription of

> Nexium, and the FDA approved in particular the 40-milligram dose in comparison to both 20-milligram doses of Nexium and 20-milligram doses of Prilosec, 20 milligrams of Prilosec being the maximum recommended dose for the same indication of healing erosive esophagitis.
>
> And when one looks at the labeling of Prilosec, one sees that not only is 20 milligrams the maximum dose of Prilosec, but the FDA declined to recommend a 40-milligram dose of Prilosec.

*Hearing transcript, Lines 3-19, pg. 10 (D.I. #47 - Exhibit A attached hereto).*

> So what plaintiffs want to call a game is, in fact, the FDA's decision to recognize that Nexium at 40 milligrams is more effective at healing erosions in the esophagus and at producing sustained resolution of heartburn symptoms for patients with erosive esophagitis than Prilosec at its maximum dose of 20 milligrams.

*Hearing transcript, Lines 19-24, pg. 13 (D.I. #47 - Exhibit A attached hereto).*

Plaintiffs respectfully request that the Court take judicial notice of the additional documents appended hereto. Plaintiffs' exhibits are actual documents from the FDA record that refute Defendants' assertions the FDA approved Nexium as superior to Prilosec. These documents consist of the following:

| **EXHIBIT** | **TAB** |
|---|---|
| NDA: 21-153, Clinical Pharmacology with Biopharmaceuticals Review, September 18, 2000. | B |
| NDA: 21-153, Medical Officer's Review, September 21, 2000. | C |
| NDA: 21-153, Approvable Letter for NDA 21-153, October 3, 2000. | D |
| NDA: 21-154, Pharmacology/Toxicology Review and Evaluation, October 31, 2000. | E |
| NDA: 21-154, Clinical and Statistical Review for New Drug Application, December 15, 2000 | F |

| | |
|---|---|
| NDA: 21-153, 21-154, Approvable Letters for 21-153, 21-154, December 15, 2000. | G |
| NDA: 21-153, Memorandum of Director, Division of Gastrointestinal and Coagulation Drug Products, February 20, 2001. | H |
| NDA: 21-153, 21-154, Approved Labeling, February, 2001. | I |

DATED: October 21, 2005

CHIMICLES & TIKELLIS LLP

Pamela S. Tikellis (#2172)
A. Zachary Naylor (#4439)
Robert R. Davis (#4536)
One Rodney Square
P.O. Box 1035
Wilmington, DE 19899
Telephone: (302) 656-2500
Facsimile: (302) 656-9053

***Interim Liaison Counsel for Plaintiffs***

Steve W. Berman
HAGENS BERMAN SOBOL SHAPIRO LLP
1301 Fifth Avenue, Suite 2900
Seattle, WA 98101
Telephone: (206) 623-7292

Barbara J. Hart
Christopher J. McDonald
GOODKIND LABATON RUDOFF & SUCHAROW, LLP
100 Park Avenue
New York, NY 10017
Telephone: (212) 907-0700

Jeffrey L. Kodroff
Theodore M. Lieveman
SPECTOR, ROSEMAN & KODROFF, P.C.
1818 Market Street, Suite 2500
Philadelphia, PA 19103
Telephone: (215) 496-0300

*Interim Co-Lead Counsel for Plaintiffs*

Thomas M. Sobol
HAGENS BERMAN SOBOL SHAPIRO LLP
One Main Street, 4th Floor
Cambridge, MA 02142
Telephone: (617) 482-3700

James R. Malone, Jr.
Michael D. Gottsch
Daniel B. Scott
Timothy N. Mathews
CHIMICLES & TIKELLIS LLP
361 W. Lancaster Avenue
Haverford, PA 19041
Telephone: (610) 642-8500

Ellen Meriwether
Bryand L. Clobes
MILLER FAUCHER & CAFFERTY LLP
One Logan Square
18th & Cherry Streets, Suite 1700
Philadelphia, PA 19103
Telephone: (215) 864-2800

L. Kendall Satterfield
Richard M. Volin
FINKELSTEIN, THOMPSON & LOUGHRAN
1050 30th Street, N.W.
Washington, D.C. 20007
Telephone: (202) 337-8000

Robert S. Schachter
Joseph Lipofsky
Paul Kleidman
ZWERLING, SCHACHTER &
ZWERLING, LLP
41 Madison Avenue, 32nd Floor
New York, NY 10010
Telephone: (212) 223-3900

Richard Kirschner
KIRSCHNER & GARTRELL
4910 Massachusetts Ave., NW, Suite 215
Washington, D.C. 20016
Telephone: (202) 775-0087

Ronald S. Goldser
ZIMMERMAN REED, PLLP
651 Nicollet Mall, Suite 501
Minneapolis, MN 55402
Telephone: (612) 341-0400

Jason J. Thompson
CHARFOOS & CHRISTENSEN, P.C.
5510 Woodward Avenue
Detroit, MI 48202
Telephone: (313) 875-8080

Jeffrey S. Goddess
ROSENTHAL MONHAIT GROSS &
GODDESS, P.A.
919 Market Street, Suite 1401
Wilmington, DE 19801
Telephone: (302) 656-4433

*Attorneys for Plaintiffs*